Research Paper ■

A Randomized Trial Comparing Telemedicine Case Management with Usual Care in Older, Ethnically Diverse, Medically Underserved Patients with Diabetes Mellitus

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Abstract **Background:** Telemedicine is a promising but largely unproven technology for providing case management services to patients with chronic conditions who experience barriers to access to care or a high burden of illness.

Methods: The authors conducted a randomized, controlled trial comparing telemedicine case management to usual care, with blinding of those obtaining outcome data, in 1,665 Medicare recipients with diabetes, aged 55 years or greater, and living in federally designated medically underserved areas of New York State. The primary endpoints were HgbA1c, blood pressure, and low-density lipoprotein (LDL) cholesterol levels.

Results: In the intervention group ($n = 844$), mean HgbA1c improved over one year from 7.35% to 6.97% and from 8.35% to 7.42% in the subgroup with baseline HgbA1c $\geq$7% ($n = 353$). In the usual care group ($n = 821$) mean HgbA1c improved over one year from 7.42% to 7.17%. Adjusted net reductions (one-year minus baseline mean values in each group, compared between groups) favoring the intervention were as follows: HgbA1c, 0.18% ($p = 0.006$), systolic and diastolic blood pressure, 3.4 ($p = 0.001$) and 1.9 mm Hg ($p < 0.001$), and LDL cholesterol, 9.5 mg/dL ($p < 0.001$). In the subgroup with baseline HgbA1c $\geq$7%, net adjusted reduction in HgbA1c favoring the intervention group was 0.32% ($p = 0.002$). Mean LDL cholesterol level in the intervention group at one year was 95.7 mg/dL. The intervention effects were similar in magnitude in the subgroups living in New York City and upstate New York.

Conclusion: Telemedicine case management improved glycemic control, blood pressure levels, and total and LDL cholesterol levels at one year of follow-up.

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The past decade has seen an explosion of interest in informatics resources that can be used directly by patients and consumers.[1] A wide variety of systems has been fielded. Patients have been given access to hospital-based electronic medical records (EMRs).[2–4] Personal health records have been developed for use directly by patients[5,6]; synchronous videoconferencing has been used for patient education, monitoring, and motivation[7–10]; and remote monitoring has been used to capture disease-specific measurements electronically, such as blood glucose or vital signs.[11–17] With the advent of the World Wide Web, Web sites have been developed to provide disease-specific education,[18,19] and e-mail has been used increasingly for interactions between patients and providers.[20–22] More recently, Web-based messaging has been viewed as a way to circumvent some of the limitations of traditional e-mails.[23–25]

Despite the number and variety of technical approaches that have been developed, several authors have noted the relative scarcity of rigorous evaluations.[26–28] The relative lack of substantive telemedicine evaluation data is related to multiple issues, including the underlying difficulty and cost of conducting robust evaluation, lack of studies using randomized

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designs with concurrent controls, small sample sizes, short-term follow-up, and lack of multidisciplinary evaluation teams. Thus, despite the obvious promise of this technology, the clinical effectiveness of telemedicine, both in general and in specific clinical contexts, remains poorly documented. The Informatics for Diabetes Education and Telemedicine project (IDEATel)[29,30] was therefore undertaken as a prospectively randomized clinical trial of health services delivered electronically directly to patients with diabetes in their homes.

Diabetes was selected as the target clinical domain for IDEATel for a number of reasons. An estimated 18 million adults in the United States have diabetes,[31] with the prevalence increasing as the population ages and obesity increases.[32,33] Type 2 diabetes accounts for 90% to 95% of diagnosed cases in adults, increases markedly with age and obesity, and is more common in African-Americans and Hispanics compared to non-Hispanic whites.[31,34] The costs of diabetes in 2002 exceeded $132 billion including $92 billion in direct medical costs.[31] Those over 65 years of age account for two thirds of all costs.[35] The chronic complications of diabetes are responsible for most of the morbidity, mortality, and cost, with most diabetes-related mortality due to macrovascular disease, specifically coronary artery and cerebrovascular disease.[36] Treatment of hypertension and dyslipidemia in patients with diabetes decreases these complications and is cost-effective.[37–43] The microvascular complications of diabetes, including neuropathy, nephropathy, and retinopathy and blindness, can be reduced by improving control of glycemia and blood pressure.[37,44–48] Thus, extensive evidence supports the benefit of improving management in type 2 diabetes for preventing morbidity and mortality from both macro- and microvascular disease.

Diabetes is frequently selected as the target condition for evaluations of telemedicine and remote monitoring because of the need for ongoing educational, motivational, and monitoring activities.[11–13,17,49,50] Access to in-person case management for diabetes may be impeded by a number of factors. In rural areas, these include geographic distance, weather, lack of public transportation, and provider shortages. In urban inner cities with predominantly minority populations, obstacles include language, culture, low educational attainment, disempowerment, lack of social reinforcement for health-related behaviors and activities, and provider shortages. Telemedicine supports patient-provider interactions that are both distant and asynchronous[51] and thereby offers the potential to improve access, the process of care, and clinical outcomes. The Centers for Medicare and Medicaid Services (CMS), the federal agency responsible for administering the Medicare program, provides only limited reimbursement for electronically delivered health care services, because of lack of data demonstrating effectiveness.[26–28]

In many ways, the IDEATel project combines features traditionally associated with telemedicine (videoconferencing and remote monitoring) with those traditionally associated with informatics (Web-based tools and integration with EMRs). The details of the IDEATel technical implementation have been described previously[30,52,53] and are reviewed briefly in the Methods section. Other articles, either published or in preparation, address various aspects including the implementation process,[54] cognitive design issues,[55,56] clinician perceptions, and patient perceptions. This article focuses on the impact of the IDEATel intervention on clinical outcomes. Specific hypotheses were that the intervention would improve hemoglobin A1c, blood pressure, and lipid levels compared to usual care.

Methods

Eligibility and Exclusions

Criteria for inclusion were age 55 years or older; being a current Medicare beneficiary; having diabetes mellitus defined by a physician's diagnosis and being on treatment with diet, an oral hypoglycemic agent, or insulin; residence in a federally designated medically underserved area (either of two federal designations, medically underserved area

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[MUA] or health professional shortage area [HPSA]) in New York State; and oral fluency in either English or Spanish. Exclusions were moderate or severe cognitive, visual, or physical impairment or the presence of severe comorbid disease. It is important to note that neither literacy nor any prior computer experience as required of subjects. In addition, no specific threshold level of HbA1c was required.

Study Design

Subjects were enrolled through primary care practices in New York City, with the enrollment hub at Columbia University Medical Center, and in upstate New York, where the enrollment hub was at State University of New York (SUNY) Upstate Medical University at Syracuse. Recruitment in the upstate area spanned a geographic area of approximately 30,000 square miles. Systematic review of patient panels was conducted at participating practices in order to identify potentially eligible patients. A total of 9,597 potential participants were identified in this fashion (Fig. 1). Eligibility was screened by telephone prior to the baseline examination and again at the baseline examination. Potentially eligible subjects were contacted by mail and telephone and invited to attend the baseline examination, where consent was obtained. Randomization to telemedicine case management or to usual care was assigned in a 1:1 ratio by the study coordinating center (Research Division of the Hebrew Home for the Aged at Riverdale) immediately upon completion of the baseline examination. Randomization began in December 2000, and was completed in October 2002. Subjects were randomized within clusters defined by primary care provider patient panels. For subjects assigned to intervention, an appointment was made by telephone for installation of the home telemedicine unit within two weeks. A follow-up examination was conducted one year after the baseline examination. Personnel conducting these examinations were blinded to intervention status and were not involved in supporting the technical aspects of the intervention or in delivering diabetes case management services. Written informed consent was obtained from all subjects. The study was approved by the Institutional Review Boards at Columbia University Medical Center, SUNY Upstate Medical University at Syracuse, and all participating hospitals and health care provider organizations.

Intervention

Participants randomized to the intervention group received a home telemedicine unit (HTU) developed specifically for IDEATel (American Telecare, Inc.; Eden Prairie, MN). The

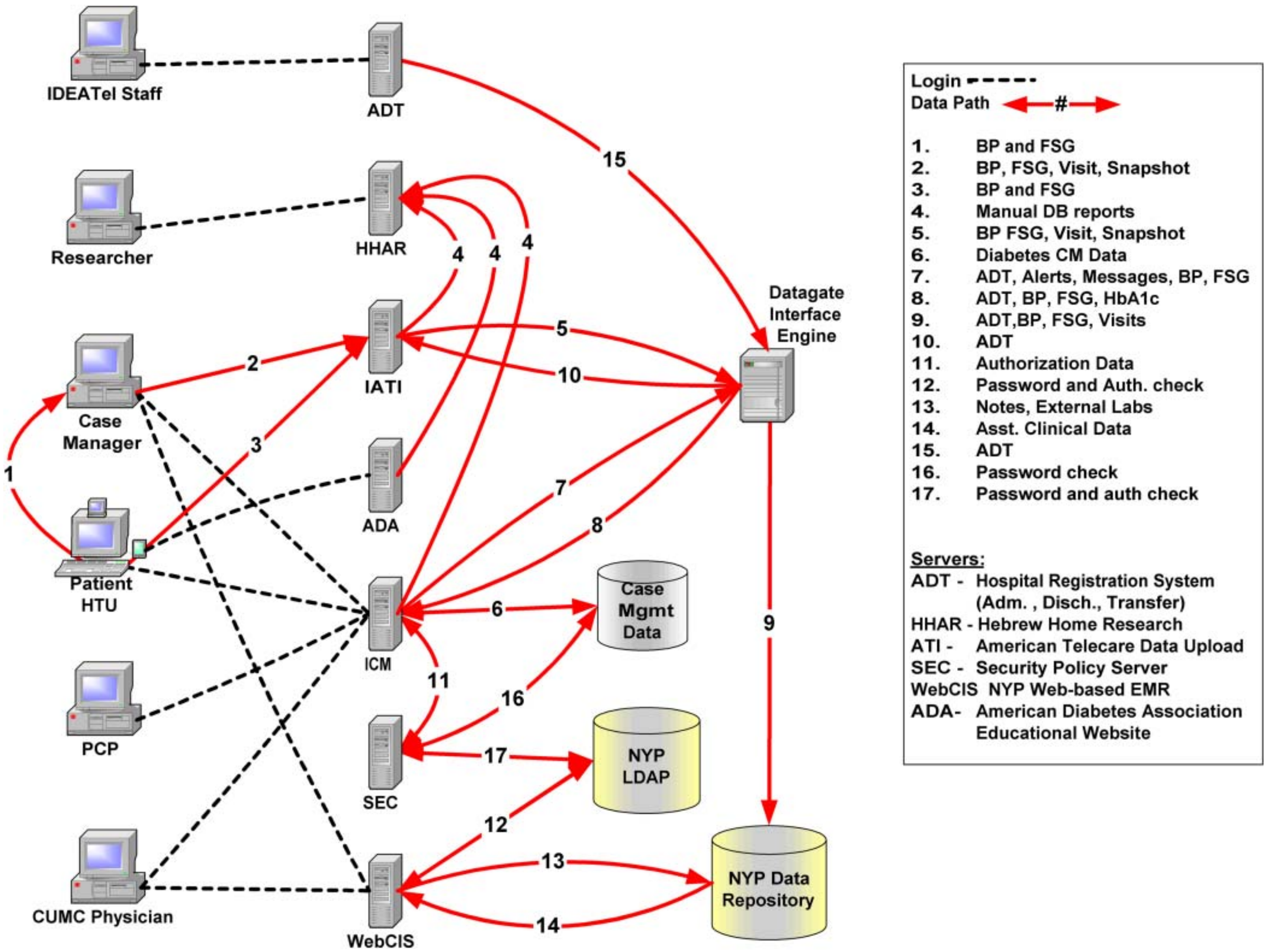

Figure 1. Logical diagram of users and data flows.

HTU consisting of a Web-enabled computer with modem connection to an existing telephone line. The HTU provided four major functions: (i) videoconferencing over plain old telephone service (POTS) connections at eight to 15 frames per second allowing patients to interact with nurse case managers at the Berrie Diabetes Center at Columbia University or the Joslin Diabetes Center at SUNY Upstate Medical University; (ii) remote monitoring of glucose (One Touch Sure Step; LifeScan, Inc.; Milpitas, CA) and blood pressure (UA-767 Blood Pressure Monitor; A&D Medical; Milpitas, CA) with electronic upload and integration with the Columbia EMR[57]; (iii) dial-up Internet service provider access to a Web portal providing access to patients' own clinical data and secure Web-based messaging with nurse case mangers; and (iv) access to an educational Web site created for the project by the American Diabetes Association in English and Spanish and in regular and low-literacy versions in each language.[30] A major goal of the technical implementation was the tight integration of the project-specific telemedicine systems with existing clinical systems through the use of well-established standards, in particular Health Level 7 (HL7).[30,52] Figure 1 summarizes the servers and data flows. Three separate methods for uploading monitoring data were provided (1,3,7 in Fig. 1). Patients can upload data directly over an SSL tunnel (3 in Fig. 1). During video visits, nurse case managers can capture data from devices connected to the HTU (1>2>5 in Fig. 1). Last, patients can log into the Web portal to manually enter results (7 in Fig. 1). All results are converted to HL7 and stored in the New York Presbyterian Data Repository. A combination of strategies provided security.[53] Project servers were placed in a firewalled subnet. Data transfers on the public Internet were encrypted. All Web access used secure socket layer encryption. Patient HTUs were secured via encrypted public key infrastructure tokens on the HTUs. Clinician access was secured through Lightweight Directory Access Protocol authentication for on-campus access and time-based cryptographic tokens (RSA Security, Bedford, MA) for remote access. A security policy server (Netegrity, Computer Associates, Islandia, NY) allowed for multiple authentication schemes based on user class.

Nurse case managers were trained in diabetes management and in the use of computer-based case management tools to facilitate interactions through videoconferencing with patients. Some subjects also received glucose test strips for the specific glucose monitor provided by the study. Subjects were trained in the use of the HTU at the time of installation and were selectively retrained during the study based on the assessment of the nurse case manager. Intervention subjects were assigned to a project case manager under supervision of diabetologists at the Joslin or Berrie Diabetes Centers (upstate and New York City subjects, respectively). Case managers interacted with patients using the HTU and case management software. We used Version 2.2b (updated May 2000) of the Veterans Health Administration Clinical Practice Guidelines for the Management of Diabetes Mellitus in the Primary Care Setting.[58] These guidelines are flexible, annotated, evidence based, and algorithmic in format. The primary care physicians of intervention patients retained full responsibility and control over their patients' care. The case managers' notes were reviewed by the supervising diabetologist, and when a change in management was suggested, the primary care physician was contacted by e-mail, fax, letter, or phone.

Usual Care

Patients in the usual care group remained under the care of their primary care providers. These primary care providers cared for patients in both the intervention and usual care groups, following the design whereby randomization was clustered within clinical practice. The primary care providers received a mailing with current guidelines for the care of patients with diabetes. The clinical care that patients in the usual care group received was delivered by their primary care providers, without other guidance or direction from study personnel.

Endpoints

Prespecified endpoints were hemoglobin A1c, blood pressure, and low-density-lipoprotein (LDL) cholesterol levels. Subjects were instructed to come to the baseline and follow-up examinations fasting and having held their glycemic control medications. For New York City subjects, all examination data were collected at Columbia University Medical Center. For Upstate subjects who could conveniently travel to Syracuse, these data were collected at the SUNY Upstate Medical University, while for those living too distant, examinations were performed in regional medical centers and medical offices. For subjects unable to travel, home visits were made by trained nurses who carried with them phlebotomy equipment, a cooler for transport of blood and urine specimens, a blood pressure device with various-size cuffs, and a scale, a stadiometer, and a measuring tape. Specimens collected in the field were spun and frozen at regional sites. Blood pressure measurements and blood and urine samples were obtained in the fasting state in the morning. After breakfast, questionnaire data were collected. Specimens were processed and frozen at the data collection sites and analyzed at Medstar Laboratory (Washington, DC). Hemoglobin A1c was analyzed by boronate affinity chromatography with the Primus CLC 385 (Primus, Kansas City, MO). Total cholesterol, triglyceride, and high-density lipoprotein (HDL) cholesterol were measured using enzymatic colorimetric methods (Vitros, Johnson & Johnson, New Brunswick, NJ). LDL cholesterol was calculated using the Friedewald equation[59] for subjects with triglyceride level <400 mg/dL and measured directly using a homogeneous assay (Polymedco, Cortlandt Manor, NY) for those with triglyceride level ≥400 mg/dL. Resting blood pressure was measured using a Dinamap Monitor Pro 100 (Critikon, Tampa, FL) automated oscillometric device. Three measurements were obtained following 5 minutes of rest using a standardized protocol.[60] The average of the second and third measurements was recorded as the resting blood pressure. Demographic and other questionnaire data were collected by interviewers at the baseline examination. Blood pressure values were communicated to participants at the time of the examination. Hemoglobin A1c and lipid levels at the baseline and follow-up examinations were communicated by mail to participants and their primary care providers for both the intervention and control groups. Data collection for the follow-up examination was completed on October 31, 2003.

Sample Size and Power Calculations

The planned sample size was 1,500, with 750 allocated to each arm of the study, based on power calculations using analysis

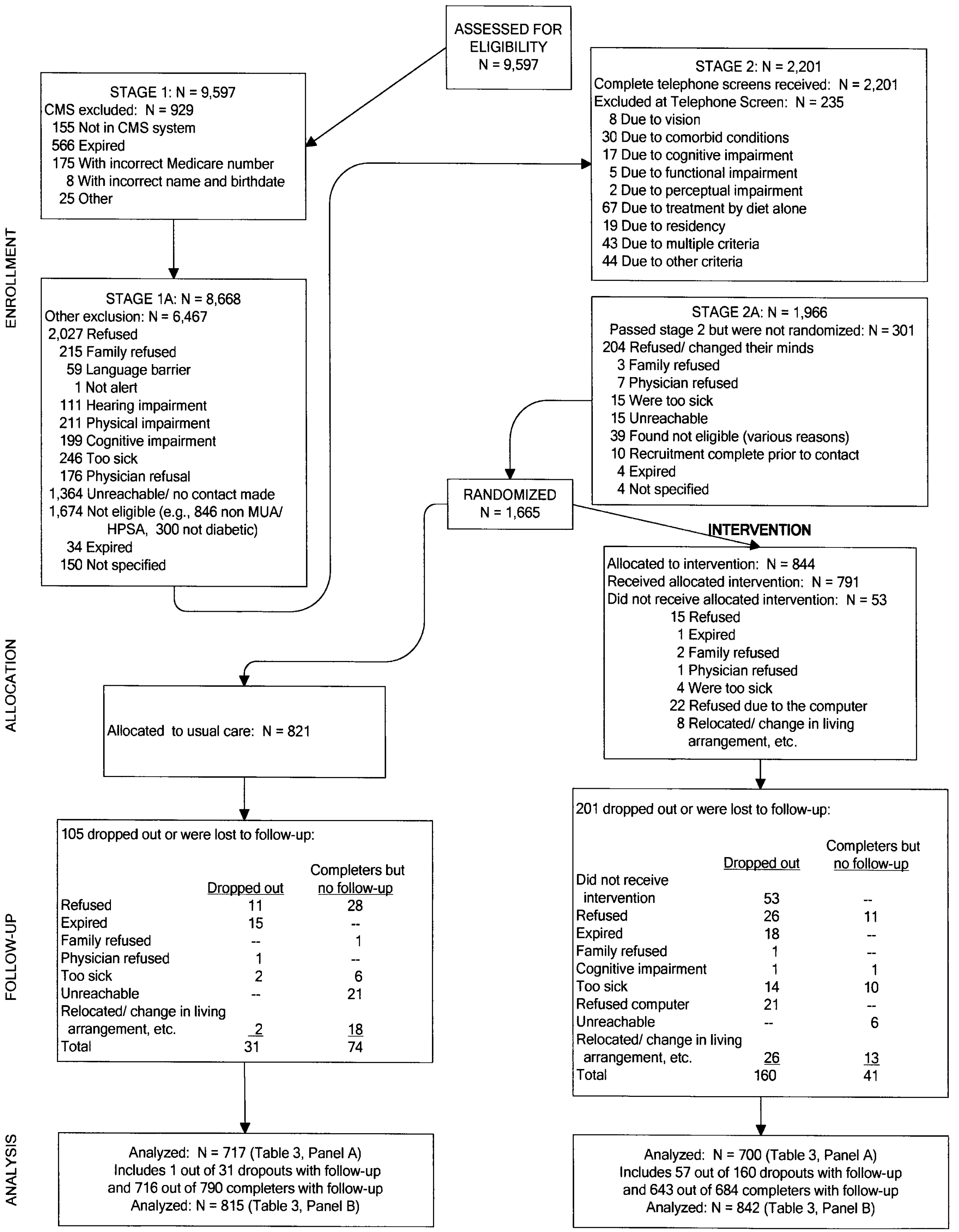

Figure 2. Study enrollment and outcomes. CMS = Centers for Medicare and Medicaid Services; HPSA = health professionals shortage area; MUA = medically underserved area. Lost to follow-up refers to randomized subjects who did not complete the follow-up examination. Dropped out refers to subjects who communicated that they wished to drop out of the study at some time during the follow-up period; some of these subjects returned for the follow-up examination. Completers refers to randomized subjects who did not drop out; some of these subjects did not return for the follow-up examination.

Table 1 ■ Baseline Characteristics of the Subjects (N = 1,665), by Treatment Group (Percentages Except Where Noted)

Characteristic	Treatment Group: Telemedicine Case Management (n = 844)	Treatment Group: Usual Care (n = 821)
Age at randomization (yr)		
55–64	12.1	11.9
65–69	33.2	34.0
70–74	26.9	25.1
75–79	17.7	18.0
≥80	10.2	11.0
Sex		
Male	36.5	37.9
Female	63.5	62.1
Race/ethnicity		
African-American (non-Hispanic)	15.3	14.5
Hispanic	35.8	34.6
White (non-Hispanic)	48.2	50.6
Other	0.7	0.2
Born in the United States		
Yes	62.0	61.1
No	38.0	38.9
Primary language		
English	63.2	62.9
Spanish	35.5	34.0
Other	1.3	3.2
Marital status		
Married/living with significant other	41.4	40.9
Single, never married	13.0	10.1
Separated/divorced	16.4	18.1
Widowed	29.1	30.7
Data missing	0.1	0.1
Lives alone		
Yes	38.1	37.1
No	61.9	62.9
Education (yr)		
0	2.1	1.6
1–11	53.6	52.5
12	28.1	28.3
≥13	16.1	17.5
Data missing	0.1	0.1
Employed		
Yes	6.6	6.0
No	93.4	94.0
Annual household income ($)		
<5,000	3.9	3.7
5,001–10,000	46.9	44.1
10,001–20,000	21.7	23.6
20,001–30,000	11.7	11.2
30,001–40,000	3.6	4.5
>40,000	5.5	5.4
Data missing	6.8	7.6
Eligible for Medicaid		
Yes	39.2	39.0
No	60.8	61.0
Participant "knows how to use a computer"		
Yes	18.8	21.2
No	79.9	78.1
Data missing	1.3	0.7

Table 1 ■ (*Continued*)

Characteristic	Treatment Group: Telemedicine Case Management (n = 844)	Treatment Group: Usual Care (n = 821)
Duration of diabetes (yr)		
<5	30.8	29.7
5–9	19.0	21.3
10–14	18.1	15.8
≥15	30.8	32.2
Data missing	1.3	1.0
Diabetes treatment		
Pills alone	65.3	65.4
Insulin alone	14.5	14.4
Insulin and pills	14.8	15.3
Diet alone	5.1	4.9
Data missing	0.4	0.0
Mean (SD) body mass index (kg/m^2)	32.1 (6.78)	31.7 (6.85)
Mean (SD) glycosylated hemoglobin (%)	7.36 (1.48)	7.40 (1.60)
Blood pressure		
Mean (SD) systolic blood pressure (mm Hg)	142.8 (24.21)	142.5 (23.62)
Mean (SD) diastolic blood pressure (mm Hg)	71.6 (11.35)	71.0 (10.42)
Lipid levels		
Mean (SD) total cholesterol (mg/dL)	182.9 (38.58)	184.9 (38.66)
Mean (SD) triglycerides (mg/dL)	169.1 (102.42)	170.9 (98.72)
Mean (SD) HDL cholesterol (mg/dL)	47.4 (14.58)	47.5 (13.45)
Mean (SD) LDL cholesterol (mg/dL)	106.6 (35.10)	108.0 (35.88)
Urine microalbumin (mg)/creatinine (g) ratio	1.54 (0.56)	1.55 (0.55)

SD = standard deviation; HDL = high-density lipoprotein; LDL = low-density lipoprotein.

of covariance and longitudinal random effects models for hemoglobin A1c and blood pressure. Power calculations were based on the following assumptions: overall attrition estimates of 20%, reliability of the outcome variables of 0.90, cluster intercorrelations ranging from 0.05 to 0.2, α = 0.05, and two-tailed test for each of the primary outcomes. Based on calculations performed assuming different scenarios regarding variances and effect sizes, power was at least 0.80 for detection of clinically meaningful changes in the outcomes. The sample size was increased during the recruitment phase of the study to compensate for differential early dropout in the intervention group.

Statistical Analysis

Analysis of covariance was used to adjust for baseline values of the outcomes and the design feature of clustering, with each primary care provider treated as a random effect. Additionally, the group heterogeneity in cluster and residual variances was modeled in order to satisfy model assumptions and improve model fit, using SAS PROC MIXED.[61] Examination of skew and kurtosis indicated that variable transformations were not required. Significance tests were two tailed, and no adjustment of p-values for multiple outcomes was applied.

Table 2 ■ Baseline Characteristics of the Subjects (*N* = 1,665), by Region of Recruitment (Percentages Except Where Noted)

Characteristic	Site: New York City (*n* = 775)	Site: Upstate New York (*n* = 890)	p-Value
Age at randomization (yr)			0.042*
55–64	10.7	13.1	
65–69	37.0	30.6	
70–74	26.3	25.7	
75–79	18.3	17.4	
≥80	7.6	13.1	
Sex			<0.001*
Male	30.5	43.0	
Female	69.5	57.0	
Race/ethnicity			<0.001*
African-American (non-Hispanic)	23.9	7.1	
Hispanic	74.1	1.3	
White (non-Hispanic)	1.0	91.5	
Other	0.9	0.1	
Born in the United States			<0.001*
Yes	22.2	95.8	
No	77.8	4.2	
Primary language			<0.001*
English	25.7	95.5	
Spanish	73.3	1.2	
Other	1.0	3.3	
Marital status			<0.001*
Married/living with significant other	27.2	53.3	
Single, never married	19.4	4.8	
Separated/divorced	22.8	12.4	
Widowed	30.5	29.4	
Data missing	0.1	0.1	
Lives alone			<0.001*
Yes	43.1	32.8	
No	56.9	67.2	
Education (yr)			<0.001*
0	3.9	0.1	
1–11	71.9	36.6	
12	17.0	37.9	
≥13	7.0	25.4	
Data missing	0.3	0.0	
Employed			<0.001*
Yes	1.8	10.2	
No	98.2	89.8	
Annual household income (dollars)			<0.001*
<5,000	4.8	2.9	
5,001–10,000	78.6	16.7	
10,001–20,000	10.6	33.1	
20,001–30,000	1.0	20.6	
30,001–40,000	0.0	7.5	
>40,000	0.5	9.7	
Data missing	4.5	9.4	
Eligible for Medicaid			<0.001*
Yes	67.4	14.5	
No	32.6	85.5	
Participant "knows how to use a computer"			<0.001*
Yes	5.4	32.7	
No	93.9	66.0	
Data missing	0.6	1.3	

Table 2 ■ (*Continued*)

Characteristic	Site: New York City (*n* = 775)	Site: Upstate New York (*n* = 890)	p-Value
Duration of diabetes (yr)			<0.032*
<5	28.5	31.8	
5–9	19.4	20.8	
10–14	17.7	16.4	
≥15	33.8	29.4	
Data missing	0.6	1.6	
Diabetes treatment			0.418*
Pills alone	64.1	66.4	
Insulin alone	14.8	14.0	
Insulin and pills	16.5	13.8	
Diet alone	4.4	5.5	
Data missing	0.1	0.2	
Mean (SD) body mass index (kg/m^2)	30.3 (6.15)	33.3 (7.05)	<0.001†
Mean (SD) glycosylated hemoglobin (%)	7.76 (1.69)	7.04 (1.30)	<0.001†
Blood pressure			
Mean (SD) systolic blood pressure (mm Hg)	142.6 (24.60)	142.7 (23.32)	0.99†
Mean (SD) diastolic blood pressure (mm Hg)	71.8(11.36)	70.8 (10.47)	0.065†
Lipid levels			
Mean (SD) total cholesterol (mg/dL)	181.6 (37.81)	185.9 (39.23)	0.02†
Mean (SD) triglycerides (mg/dL)	144.9 (85.19)	192.2 (107.74)	<0.001†
Mean (SD) HDL cholesterol (mg/dL)	49.7 (14.99)	45.4 (12.80)	<0.001†
Mean (SD) LDL cholesterol (mg/dL)	105.5 (34.58)	108.9 (36.21)	0.057†
Urine microalbumin (mg)/creatinine (g) ratio	1.53 (0.57)	1.55 (0.53)	0.33

SD = standard deviation; HDL = high-density lipoprotein; LDL = low-density lipoprotein.
*Analysis of variance or χ^2 test.
†t-test.

Results

Recruitment, enrollment, randomization, and completion of the follow-up examination are shown in Figure 2. The one-year follow-up examination was not completed by 248 of the 1,665 randomized subjects (14.9%), of whom 144 were assigned to intervention and 104 to usual care.

The intervention and usual care groups did not differ with respect to baseline demographic and clinical characteristics (Table 1). Mean age was approximately 71 years (median, 70) in both groups. Subjects living in the New York City region were younger, more likely to be Hispanic and African American, have lower educational attainment and annual household income, to be eligible for Medicaid, to live alone, and to respond "no" to the question "Do you know how to use a computer?" compared to subjects living in the Upstate region (Table 2).

At one year of follow-up, mean hemoglobin A1c level decreased in the intervention group from 7.35% to 6.97% (Table 3, panel A). The net adjusted reduction in hemoglobin

Table 3 ■ Differences at One Year of Follow-up in Clinical Outcomes between Intervention and Usual Care Groups, Adjusted for Clustering and for Group Heterogeneity in Cluster and Residual Variances

	*N*s for Analysis		Baseline					One-Year Follow-up					
			Usual Care		Intervention			Usual Care		Intervention			
Outcome Variable	Usual Care	Intervention	Mean	SD	Mean	SD	t-Test p-Value	Mean	SD	Mean	SD	Adjusted Difference Score	ANCOVA p-Value
A: Subjects who completed the baseline and one-year follow-up examinations													
Hemoglobin A1c (%)	685	670	7.42	1.58	7.35	1.41	0.41	7.17	1.40	6.97	1.12	−0.18 (−0.20)	0.006
Hemoglobin A1c (%) in subgroup with A1c ≥7% at baseline	353	352	8.52	1.47	8.35	1.24	0.10	7.78	1.47	7.42	1.19	−0.32 (−0.36)	0.002
Systolic blood pressure (mm Hg)	709	697	141.75	23.47	142.13	23.13	0.76	140.62	22.92	137.40	21.24	−3.42 (−3.22)	0.001
Diastolic blood pressure (mm Hg)	709	697	70.91	10.47	71.42	11.21	0.37	70.05	11.05	68.44	9.91	−1.94 (−1.61)	<0.001
Total cholesterol (mg/dL)	679	666	184.89	38.56	182.89	37.27	0.33	182.64	41.72	170.70	35.52	−11.06 (−11.94)	<0.001
LDL cholesterol (mg/dL)	678	664	107.97	35.48	106.40	33.54	0.41	105.92	39.62	95.69	31.77	−9.50 (−10.23)	<0.001
B: All randomized subjects, with baseline data carried forward for subjects who did not complete the one-year examination													
Hemoglobin A1c (%)	802	829	7.40	1.60	7.36	1.48	0.62	7.19	1.45	7.05	1.28	−0.12 (−0.14)	0.04
Hemoglobin A1c (%) in subgroup with A1c ≥7% at baseline	406	433	8.53	1.49	8.40	1.33	0.18	7.90	1.52	7.65	1.37	−0.20 (−0.25)	0.03
Systolic blood pressure (mm Hg)	815	842	142.47	23.62	142.79	24.21	0.79	141.49	23.18	138.87	22.92	−2.86 (−2.62)	0.003
Diastolic blood pressure (mm Hg)	815	842	71.01	10.42	71.59	11.35	0.28	70.26	10.94	69.12	10.40	−1.54 (−1.14)	<0.001
Total cholesterol (mg/dL)	796	823	184.93	38.66	182.87	38.58	0.28	183.01	41.38	173.00	37.53	−8.82 (−10.01)	<0.001
LDL cholesterol (mg/dL)	795	823	107.97	35.88	106.64	35.10	0.45	106.23	39.40	98.00	34.08	−7.40 (−8.23)	<0.001

Adjusted difference score refers to the difference between intervention and usual care groups adjusted for the baseline value of the variable. Values in parentheses are actual (unadjusted) differences. ANCOVA (analysis of covariance) was used to compute a test statistic on the difference between groups at one year adjusted for the baseline value of the variable.
SD = standard deviation; LDL = low-density lipoprotein.

A1c in the intervention group compared to the usual care group was 0.18% ($p = 0.006$), despite a reduction in the control group from 7.42% to 7.17% over this time (Table 3, panel A). In the intervention subgroup with hemoglobin A1c ≥7% at baseline ($n = 353$), mean A1c level decreased from 8.35% to 7.42%, with net adjusted reduction of 0.32% ($p = 0.002$). For the study sample as a whole, mean systolic and diastolic blood pressure level decreased in the intervention group from 142/71 mm Hg to 137/68 mm Hg. The net adjusted reductions for systolic and diastolic blood pressure were 3.4 mm Hg ($p = 0.001$) and 1.9 mm Hg ($p < 0.001$). For total and LDL cholesterol these net adjusted differences were 11.06 mg/dL and 9.5 mg/dL ($p < 0.001$ for both). Changes over one year in the control group in blood pressure and lipid levels were small. Mean LDL cholesterol level in the intervention group at one year was 95.7 mg/dL.

Subjects who did not complete the one-year follow-up examination did not differ from those who did at the $p \geq 0.05$ level with respect to age, sex, race/ethnicity, and baseline levels of hemoglobin A1c, blood pressure, and LDL cholesterol. Findings from analyses in which the baseline values of subjects who did not complete the one-year follow-up examination were carried forward as the one-year follow-up value, and with the same statistical adjustments as in the main analysis, were consistent with the main findings (Table 3, panel B).

One-year follow-up results were also analyzed separately in the Upstate New York and New York City regions because of the baseline differences in subjects recruited in the two areas and also because of the potential for heterogeneity in the intervention, which was delivered to each of these two groups of subjects from a single diabetes center in Syracuse or New York City, respectively. The intervention effect was similar in magnitude in the two regions for each of the clinical outcomes (Table 4, panels A and B). Intervention subjects made extensive use of the home telemedicine system (Table 5). All aspects of the system received greater utilization by subjects in the Upstate region compared to those in New York City.

The cost to the project of the home telemedicine unit was $3,425 per unit ($3,000 for the patient station, $225 for the blood pressure cuff, $75 for cables, and $125 for the cart). The home glucometers were provided to the project at no cost by LifeScan, Inc. The quoted cost for the glucometer and cable was $110.

Discussion

We found that diabetes case management delivered using telemedicine improved hemoglobin A1c, blood pressure, and LDL cholesterol levels in older patients with diabetes mellitus at one year of follow-up compared to usual care. Intervention effects of approximately the same magnitude were observed in both urban and rural subgroups. The intervention effect on diabetes control was greater in the subgroup with hemoglobin A1c ≥7% at baseline, with an absolute change from 8.35% to 7.42% and a difference net of change in the usual care group of 0.32%. Entry into the study required residence in federally designated medically underserved geographic areas. Because of the high concentration of people with low income living in these areas, the study group had high

Table 4 ▪ Analyses at One Year of Follow-up for Upstate New York and New York City Subgroups Separately, Showing Differences in Clinical Outcomes between Intervention and Usual Care Groups, Adjusted for Clustering and Heterogeneity in Cluster and Residual Variances

	*N*s for Analysis		Baseline					One-Year Follow-up					
			Usual Care		Intervention			Usual Care		Intervention			
Outcome Variable	Usual Care	Intervention	Mean	SD	Mean	SD	t-Test p-Value	Mean	SD	Mean	SD	Adjusted Difference Score	ANCOVA p-Value
A: Upstate New York													
Hemoglobin A1c (%)	339	338	7.01	1.22	7.05	1.25	0.65	6.87	1.25	6.75	0.92	−0.18 (−0.12)	0.03
Hemoglobin A1c (%) in subgroup with A1c ≥7% at baseline	148	154	8.05	1.09	8.05	1.17	1.00	7.51	1.36	7.14	0.97	−0.50 (−0.37)	0.001
Systolic blood pressure (mm Hg)	362	364	142.12	22.86	142.13	22.96	1.00	139.87	23.98	135.97	21.51	−3.98 (−3.90)	0.006
Diastolic blood pressure (mm Hg)	362	364	70.91	10.10	70.80	11.09	0.88	69.59	10.93	67.53	9.63	−2.13 (−2.06)	0.003
Total cholesterol (mg/dL)	337	338	186.55	38.72	185.75	38.23	0.79	179.31	42.10	169.57	36.01	−10.02 (−9.74)	0.001
LDL cholesterol (mg/dL)	336	336	108.60	35.98	108.42	34.30	0.95	101.62	38.04	95.04	30.90	−6.89 (−6.58)	0.01
B: New York City													
Hemoglobin A1c (%)	346	332	7.82	1.77	7.66	1.50	0.19	7.45	1.49	7.19	1.26	−0.18 (−0.26)	0.06
Hemoglobin A1c (%) in subgroup with A1c ≥7% at baseline	205	198	8.86	1.61	8.59	1.25	0.06	7.98	1.52	7.64	1.30	−0.23 (−0.34)	0.10
Systolic blood pressure (mm Hg)	347	333	141.37	24.11	142.12	23.34	0.68	141.40	21.77	138.96	20.87	−2.76 (−2.44)	0.06
Diastolic blood pressure (mm Hg)	347	333	70.90	10.86	72.10	11.32	0.16	70.54	11.17	69.44	10.13	−1.73 (−1.10)	0.02
Total cholesterol	342	328	183.26	38.39	179.95	36.07	0.25	185.92	41.15	171.86	35.01	−12.23 (−14.06)	<0.001
LDL cholesterol (mg/dL)	342	328	107.35	35.03	104.34	32.66	0.25	110.14	40.72	96.34	32.67	−12.25 (−13.80)	<0.001

Adjusted difference score refers to the difference between intervention and control groups adjusted for the baseline value of the variable. Values in parentheses are actual (unadjusted) differences. ANCOVA (analysis of covariance) was used to compute a test statistic on the difference between groups at one year adjusted for the baseline value of the variable.
SD = standard deviation; LDL = low-density lipoprotein.

proportions of subjects with Medicaid eligibility, of Hispanic and African American race/ethnicity, and with low levels of educational attainment and computer familiarity. Nonetheless, the computer-dependent intervention strategy met with a high level of acceptance, was used, and had favorable effects on the main outcomes.

Diabetes control in the usual care group, as measured by mean hemoglobin A1c level, improved over the one year of follow-up by 0.25%, from 7.42% to 7.17%. In the subgroup with hemoglobin A1c ≥7.0% at baseline, this change was 0.74%, from 8.52% to 7.78%. These improvements in the usual care group are consistent with secular trends in improved diabetes care nationally,[62] spill-over effects of the intervention, or both. Secular trends in diabetes care may have resulted from national educational and quality improvement programs,[63,64] publication of standards of care,[65] and recent availability of new classes of drugs.[66] Spill-over effects may have occurred because all participating physicians received educational materials on diabetes management as well as communications from the study case managers regarding management of specific intervention patients. The study design randomized subjects within physician practices. Although the average cluster size was small (mean, 3; median, 1), many participating physicians managed patients in both the intervention and control groups. Reporting of baseline hemoglobin A1c to participants and their physicians may also have contributed to improved glycemic control in both groups. These contexts may explain the relatively smaller clinical impact of the intervention, net of changes in the control group, on hemoglobin A1c.

The follow-up examination was not completed by 248 of the 1,665 randomized subjects, of whom 144 were randomized to intervention and 104 to usual care. Information obtained by study staff from intervention subjects who dropped out suggests that the differential loss to follow-up was due largely to factors related to the HTU, including its physical size and difficulties subjects experienced in learning how to use it. The dropout rate for the intervention subjects cannot be directly compared with most other telemedicine or remote monitoring studies for several reasons. First, very few other telemedicine intervention studies continued for one year or more. Second, few used an intention-to-treat analysis.[67] In particular, in our study, patients who were randomized to the intervention group but never had HTUs installed due to poor telephone line quality were counted among the intervention dropout group.

Very few subjects in our study who were able to use the device effectively dropped out, and the dropout rate was greater among those in the intervention group who experienced difficulty using the home telemedicine device. Thus, loss to follow-up was not random. We attempted to address the issue of loss to follow-up by performing an analysis with the baseline value carried forward.[68] The results of this analysis showed that the intervention effects remained significant, assuming that those who dropped out did not experience worsening of mean hemoglobin A1c, blood pressure, and lipid levels over the year following randomization.

Table 5 ■ Home Telemedicine System Use by Intervention Participants, 7/1/01–10/31/03

	Completed Home Televisits	Home Fingerstick Glucose Uploads	Home Blood Pressure Uploads	Visits to the Patient Data Review Web Site	Visits to the Educational Web Site
New York City	7,691	144,098	38,293	7,731	479
No. of participants	351	339	301	328	193
Mean	21.91	425.07	127.22	23.57	2.48
SD	9.75	349.84	185.36	87.95	3.29
Median	24	368	67	6	2
Upstate New York	14,040	270,433	85,414	27,873	662
No. of participants	418	401	369	397	208
Mean	33.59	674.4	231.47	70.21	3.18
SD	16.88	482.34	233.92	193.62	4.64
Median	35	575	148	10	2
Total	21,731	414,531	123,707	35,604	1,141
No. of participants	769	740	670	725	401
Mean	28.26	560.18	184.64	49.11	2.85
SD	15.23	444.25	219.55	156.65	4.06
Median	28	494	98.5	7	2

The patient data review Web site provided displays of uploaded home glucose and blood pressure values.

We compared diabetes case management delivered using telemedicine to usual care, which for most patients did not incorporate case management. Comparison of telemedicine versus in-person delivery of diabetes case management would not have been feasible across the geographic span of the State of New York, nor would such a design have addressed the question whether telemedicine is an effective strategy for improving diabetes care compared to currently available patterns of care. Another feature of our design was that all medication changes were made by the primary care physicians rather than directly by the nurse case managers, so that the diabetes case management was embedded within the primary care process. Although primary care physicians were offered secure Web-based messaging, most preferred to interact with nurse case managers through traditional communication media, telephone, and fax. Not all recommendations for medication changes from the intervention team were implemented by the primary care practitioners. We did not compare diabetes case management and primary care for patients with diabetes.

Our findings are generally consistent with those of smaller studies of telemedicine as a means of providing care for patients with diabetes that reported patient acceptance, improved glycemic control, or both.[13,67,69–72] The IDEATel project, however, differs from prior studies in a number of ways. The most obvious difference is scale. The IDEATel results indicate that the benefits described in smaller studies can be delivered to large numbers of patients across broad geographic expanses and substantial sociodemographic diversity. To our knowledge, it is the first telemedicine study to report simultaneous improvements in HbA1c, blood pressure, and lipids. The study is also unusual in that the recruitment process did not target patients with poor glycemic control, nor did it require computer experience or computer literacy for eligibility. As such, we believe it may be more representative of the population at large. Previous telemedicine studies have been based in individual clinical practices or small groups of practices.[13,16,17,49,67,72,73] Unlike most other studies, IDEATel included large numbers of medically underserved and ethnic minority subjects. The IDEATel intervention spanned hundreds of independent practices. Most prior studies have used stand-alone systems. The IDEATel system demonstrates the feasibility of tight, standards-based integration between a remote case management system and a large EMR. It also demonstrates the feasibility of data capture directly from home monitoring devices into a longitudinal, comprehensive EMR. From an informatics research standpoint, this study demonstrates that large-scale, prospectively randomized clinical trials of informatics interventions are possible.

A number of obstacles remain to be overcome before the full potential of telemedicine can be brought to bear on the health care delivery system. Foremost among these is the cost of technology and personnel for effective case management. The cost to the project of the home telemedicine devices was $3,425. In addition, Medicare claims were greater in the intervention group compared to the usual care group during the one year of follow-up, a finding consistent with the fact that enrollment occurred only in federally designated medically underserved areas and with the inference that the intervention contacts increased needed use of health care services. A full analysis of Medicare claims and project-related intervention costs will be reported separately. Other obstacles to the use of telemedicine and the Internet in health care include lack of data system resources for providers to capture and respond to uploaded data, reimbursement models, and state medical licensing regulations that require telemedicine-based providers to be in the same state as patients.[74,75] Some of these barriers are being addressed in part by rapidly evolving technical solutions that are smaller, portable, less expensive, more familiar, and easier to use. The IDEATel study provides evidence that medical informatics and telemedicine technology can help to translate advances in treatment of chronic diseases into effective health care. Our study also provides evidence that the "digital divide"[76] is an addressable rather than an insurmountable obstacle to use of computer-based technology to improve care for chronic conditions for many patients with limitations in access. The implication is that telemedicine has the potential to be an effective means of providing case management for older persons with diabetes and possibly for other groups as well.

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